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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,268	07/07/2005	John L. Schenk	XY-lowPressure-USNP	5591
33549 7590 08/08/2008 SANTANGELO LAW OFFICES, P.C. 125 SOUTH HOWES, THIRD FLOOR FORT COLLINS, CO 80521				
EXAMINER NOBLE, MARCIA STEPHENS				
ART UNIT 1632		PAPER NUMBER		
NOTIFICATION DATE 08/08/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/523,268

Applicant(s)

SCHENK ET AL.

Examiner

MARCIA S. NOBLE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 31, 39-52 and 62-72 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 and 62-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 31, 39, 40 and 65-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/10/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/10/2008 has been entered.

Status of Claims

2. Claims 1-3, 8, 31, 39-52, and 62-72 are pending. Claims 41-52 and 62-64 are withdrawn from consideration as nonelected subject matter. Claim 1 is amended, claims 4-7 and 53-61 are canceled, and claims 66-72 are added by the amendment filed 7/10/2008. Claims 1-3, 8, 31, 39, 40, and 65-72 are under consideration.

Withdrawn Rejections

3. a) The rejection of claims 1-8, 31, and 39-64 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as set forth in the Office Action, mailed 2/26/2007, is withdrawn.

b) The rejection of claims 1-4, and 8, under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS), as set forth in the Office Action, mailed 2/26/2007, is withdrawn.

c) The rejection of claims 1-4, 8, 9, 39, and 40, under 35 U.S.C. 102(b) as being anticipated by Beyhan et al (Theriogenology 53:35-48, 1999; of record), as set forth in the Office Action, mailed 2/26/2007, is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5-8, 31, 39, 40, and 65-72, as amended, previously presented, and newly added are rejected under 35 U.S.C. 102(b) as being anticipated by Seidel et al (WO 99/33956 pub date:7/8/1999; of record in IDS), as set forth in the Office Action, mailed 2/26/2007 on pages 9-10.

Applicant's arguments filed 7/10/2008 have been fully considered but they are not persuasive. Applicant asserts that Seidel et al does not teach or suggest "altering flow characteristics of said fluid stream to adjust fluid stream pressure between at least two different fluid stream pressures...", as recited by the amended claim 1 and the newly added claims 65-72 (see p. 11 last par, line 1 to p. 12, par 1, line 5 of remarks).

Applicants arguments are not found persuasive because Seidel et al discloses that the flow cytometry for sperm sorting can be adjusted to "50 pounds per square inch and even 60 and higher pounds per square inch" (p. 11, lines 22-24). This disclosure by Seidel et al encompasses the new limitation of "altering flow characteristics of said

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fluid stream to adjust fluid stream pressure **between** at least two different fluid stream pressures...", because Seidel et al is offering a range of at least two or more different pressures to which the fluid stream pressure can be adjusted.

Also, because the claims recite "about" 40 psi for viability and the specification does not define a range that would be encompassed by "about 40 psi", 50 or even 60 psi would be encompassed by "about 40 psi", given its broadest reasonable interpretation. Therefore, the claims are still anticipated by Seidel et al. and the rejection of record is maintained.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description/New Matter

5. Claims 1-3, 8, 31, 39, 40, and 65-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 and new claim 65 recite, "altering flow characteristics of said fluid stream to adjust fluid stream pressure **between** at least two different fluid stream pressures". The breadth of this recitation encompasses using at least two different fluid

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stream pressures for sorting a semen sample. However, the specification does not convey that applicant had ever contemplated such a delivery. Applicant cannot possess that which they have not contemplated.

MPEP 2163.02 states:

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). The subject matter of the claim need not be described literally (i.e., using the same terms or in *haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

The present specification provides no such reasonable clarity to those skilled in the art that Applicant was in possession of the claimed invention. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. Applicant,

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therefore, has not reasonably conveyed this concept through the disclosure at the time of filing, and thus the amendment to claim 1 and the newly added claim 65 lack adequate written description. Applicant must either show support for the amendment in the specification or cancel the amendment.

Claims 2, 3, 8, 31, 39, 40, and 66-72 depend upon claims 1 and 65.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3, 8, 31, 39, 40, and 65-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 and new claim 65 recite, "between at least two different fluid stream pressures". The metes and bounds of this recitation are indefinite because "between" suggests that the fluid stream pressure falls within a range of pressures. However, the claims do not recite a range of pressures. Furthermore, following this recitation the claims recite specific pressures to be used. Therefore, it is not clear if the claims are intended to encompass a range of pressures or specific pressure to be used. Also, it is not clear from this recitation if the claims are meant to be drawn to a fluid stream that is adjusted to two different pressures (i.e.- the sperm sample is subjected to two different pressures) or if the fluid stream is meant to be adjusted and set a one fluid

pressure that falls between at least two different fluid stream pressures (i.e.- the sperm sample is subjected to one pressure).

Claim 1 and 65 also recite, "viability" and "cleavage rate". These recitations are indefinite because it is unclear to what "viability" and "cleavage rate" are referring.

Claims 1 and 65 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: subjecting the semen sample to the fluid stream having a selected fluid stream pressure associated with said selected fertility characteristic.

The claims recite the method steps of obtaining a semen sample, generating a fluid stream, selecting a fertility characteristic, altering flow characteristics of said fluid stream, controlling said selected fertility characteristic, and generating a sperm cell sample. However, the never actually applies the semen sample to the fluid stream pressure.

Claims 2, 3, 8, 31, 39, 40, and 66-72 depend upon claims 1 and 65.

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

Marcia S. Noble
AU 1632